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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,577	03/21/2005	Ulrich Speck	WEICKM-44	8523
23599 7590 10/05/2007 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			EXAMINER BOUCHELLE, LAURA A	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 10/05/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/528,577

Applicant(s)

SPECK ET AL.

Examiner

Laura A. Bouchelle

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3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 3/21/05, 8/24/06.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Drawings***

1. The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81(c). No new matter may be introduced in the required drawing. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-9, 11, 14-20, 22-29, 31, 37-42, 44-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Bates et al (US 2004/0073284).

4. Bates discloses a coated medical device comprising a lipophilic drug adhered to the surface of a medical device; the drug is released immediately upon contact with the tissue. The drug is carried on a balloon 26 having longitudinal folds 46, 48, 50 (Page 10, paragraph 0092). See Fig. 7. The drug may be paclitaxel (Page 2, paragraph 0014).

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5. Claims 5 are considered to be product by process claims. These claims are not limited to the manipulations of the recited steps, only the structure implied but the steps. The patentability of a product does not depend on its method of production. See MPEP 2113.
6. Bates discloses that the drug is in suspension that is sprayed on to the device in an ethanol solution (Page 8, paragraph 0068). The device of Bates may be used to treat vascular disease (paragraph 003) or a tumor (paragraph 0055).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 10, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bates in view of Desai et al (US 5916596).
9. Claims 10, 30 call for the drug to include amorphous structures with particle sizes ranging from 0.1 to 5 microns. Bates teaches that the drug is a quick dissolving lipophilic drug such as paclitaxel but fails to disclose the particle size. Desai teaches that it is known in the art to use paclitaxel particles having a diameter of less than one micron so that the drug can be delivered in vivo. See Abstract. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Bates to have the drug in particles of

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less than about one micron as taught by Desai so that the drug can be delivered in vivo regardless of its water solubility.

10. Claims 11-13, 31, 32, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bates in view of Barry et al (US 6306166).

11. Claims 11-13, 31, 32, 36 differ from Bates in calling for the drug to be embedded in a readily water-soluble matrix, the matrix to be a low molecular weight hydrophilic substance. Barry teaches loading and release of water insoluble drugs such as paclitaxel in a low molecular weight matrix that allows the drug to be adhered to a medical device and still be absorbed into the tissue (Col. 15, lines 16-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Bates to have the drug embedded in a low molecular weight matrix as taught by Barry so that the drug can have good adhesion to the medical device and be readily absorbed by the tissue.

12. Claims 21, 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bates in view of Ding et al (US 6364856).

13. Claims 21, 43 differ from Bates in calling for the device to be sterilized using ethylene oxide. Ding teaches a medical device with a coating for controlled drug release similar to that of Bates, but further including the step of sterilizing the device using ethylene oxide as is well known in the art (Col. 6, lines 57-59). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Bates to include the step of sterilizing the device using ethylene oxide as taught by Ding because it is well known that

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devices to be inserted into a patient need to be sterilized and using ethylene oxide is an established technique for sterilization of medical devices.

14. Claims 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bates in view of Barry as applied to claim 31 above, and further in view of Klaveness et al (US 6177061).

15. Claims 33-35 differ from the teachings above in calling for the matrix to be a contrast agent, and the contrast agent is iopromide. Klaveness teaches the use of iopromide in a matrix material so that the matrix can be visualized when it is inside the body using x-ray (Col. 7, lines 14-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Bates in view of Barry so that the matrix is formed of the contrast agent iopromide as taught by Klaveness so that the substance can be visualized using x-ray.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle  
Examiner  
Art Unit 3763



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